**UNITED STATES DEPARTMENT OF COMMERCE**
**Patent and Trad mark Offic**
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/269,874 | 08/02/99 | BUJARD | H 402162000200 |

HM22/1219

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| EXAMINER | |
|---|---|
| GRUN, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | 25 |

**DATE MAILED:** 12/19/00

**Please find below and/or attached an Office communication concerning this application or pr ceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/269,874 | BUJARD et al. |
| **Examiner** | **Group Art Unit** |
| James L. Grun, Ph.D. | 1641 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *42-82* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *42-82* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application clearly fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Failure to comply with these requirements will result in ABANDONMENT of the application. Applicant is requested to return a copy of the attached Notice to Comply with the response.

In the examination of international applications filed under the Patent Cooperation Treaty, PCT Rule 13.1 states that the "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')".

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, one of the following three possible combinations of claims of different categories in the same international application:

(1) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of said product, and an independent claim for a use of said product, or

(2) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out said process, or

(3) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of said product, and an independent claim for an apparatus or means specifically designed for carrying out the process.

Unity of invention is fulfilled only when a group of inventions is linked in technical relationship by at least one corresponding technical feature (i.e. the inventions are not independent), wherein the corresponding technical feature(s)is(are) "special" under PCT Rule 13.2, i.e. a contribution over the prior art.

This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept. Under PCT Rule 13 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required:

I. Claims 42-49 and 53-57, drawn to a method of producing a protein.

II. Claims 50-52, drawn to a method of producing a nucleotide sequence.

III. Claims 58-69, 70-72, 73-78, and 81, drawn to a group of related products (encoding nucleic acids, vectors comprising the nucleic acids, and host cells comprising the nucleic acids) sharing a technical feature (i.e. nucleic acids).

IV. Claim 80, drawn to a given product (vaccine composition).

V. Claim 79, drawn to a therapeutic method using a protein product.

VI. Claim 82, drawn to a method of stabilizing a gene sequence.

The inventions listed as Groups I-VI do not meet the requirements for Unity of Invention for the following reasons:

The International Preliminary Examination Report has indicated that the broadly claimed inventions are clearly anticipated by the prior art cited therein. Moreover, the broadly claimed nucleic acid products (Group III) and compositions (Group IV) and the methods of using these products and compositions (Group I) are products/methods of nature and, therefore, the claimed inventions share no "special" technical feature (e.g. the encoding sequences for the MSP-1 protein of *Plasmodium vivax* have a lower A+T content than those encoding the MSP-1 protein of *Plasmodium falciparum*).

The nucleic acid sequences do not depend upon the method of Group II for their production.

The therapeutic use of Group V does not depend upon making the protein with any particular method such as the method of Group I.

The stabilizing method of Group VI does not require any of the nucleic acid products or compositions as claimed.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., Technology Center 1600, Group 1640, Art Unit 1641, whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice To Comply.

James L. Grun, Ph.D.
December 17, 2000

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Application No.: 09/269,874

# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

## Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**